REMARKS

This is responsive to the Final Action dated May 17, 2001. Reconsideration is respectfully requested in view of the following remarks.

Claims 1-4 are now pending.

Rejection under 35 U.S.C. 102(e)

The Examiner rejects claims 1-4 under 35 U.S.C. 102(e) as being anticipated by Kochel (U.S. pat. no. 5,849,196).

Before addressing the issue of anticipation, applicant will briefly describe the processes of making the three related products at issue, i.e. the "conventional Reticulose", Kochel's composition and applicant's Product R, and the differences therebetween.

The process of making the "conventional Reticulose" is described by Kochel in Col. 5 where the starting materials are listed in the following table:

RAW MATERIALS 9(10L)	AMOUNTS	WEIGHT PERCENTAGE
Casein	250 grams	43.9%
blood albumin	15 grams	2.6%
beef peptone	150 grams	26.3%
nucleic acid (RNA)	80 grams	14.0%
sodium hydroxide	75 grams	13.2%

According to Kochel, the above starting materials eventually yield a final product having "molecular weight of the active components ranges from approximately 1- 25 kDa."

As a modification of the conventional Reticulose, Kochel distinguishes his composition from the conventional Reticulose by further processing the conventional Reticulose through a dialysis process to remove lower molecular weight components. "The threshold for molecular weight (MW) of molecules removed or separated by dialysis according to the invention is in the range of 8-15 kDa." Thus, Kochel essentially divided the "conventional Reticulose" into two

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parts: the high molecular weight components (MW>8-15 kDa) and the lower molecular weight components (MW < 8-15 kDa). The high molecular weight components are claimed.

It should be noted, nowhere in Kochel's patent does Kochel use the term "Reticulose" or "Product R" for his product. On the contrary, throughout the text of his entire patent, he made it clear and unequivocal that his product was derived from Reticulose but is not the "conventional Reticulose".

The "conventional Reticulose" is a proprietary product of the assignee of the present application, namely, Advanced Viral Research Corp. (ADVR). The "conventional Reticulose was developed by the predecessor in interest of ADVR many years ago. The term "Reticulose" is ADVR's registered trademark. Over the years, the recipe and the process of making the "conventional Reticulose" have been continuously modified and tested. In fact, the manufacture of the "conventional Reticulose" has been long discontinued. At least since 1960's, many new products have been developed and replaced the "conventional Reticulose". Product R is ADVR's most recently developed product based on the technology of the "conventional Reticulose" but made by a process significantly different from that for making the "conventional Reticulose".

Unlike Kochel's product, which starts with the recipe of the "conventional Reticulose" and results from further processing the "conventional Reticulose", Product R start with a materially different recipe, which are demonstrated in the following table in comparison with the recipe for the "conventional Reticulose".

Starting Materials (in 10 L)	Reticulose	Product R
Casein	***250 grams***	***140 grams***
Beef peptone	***150 grams***	***68.4 grams***
Serum albumin	15 grams	13 grams
RNA	80 grams	88 grams
NaOH	75 grams	66 grams

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Simply put, the protein contents (casein and beef peptone) of the starting materials for Product R are dramatically reduced compared to that of the "conventional Reticulose".

Other than the above demonstrated protein contents, there are also material differences between the two processes, such as the length of time for the cooling period after the autoclave treatment, which ultimately affects the final composition of the product. These differences, which can be readily determined simply by comparing the two processes, are sufficient to lead the conclusion that Product R and the "conventional Reticulose" are two distinct products.

Indeed, the following data supports the fact that "Product R" has evolved to become a product different from the "conventional Reticulose" in its composition and biological functions, as a result of modification of the process.

	UV Absorbance		Inhibition of Phagocytosis
	$A_{260/280}$	$A_{260/230}$	
Reticulose	2.839	1.198	No
Product R	1.998	1.359	Yes

The composition differences among Product R, Reticulose and Kochel's product are also clearly shown by their UV Absorbances, attached herewith. Although these data became available only after the present application was filed, they are inherent properties of the two products, which were possessed by these two products at the time the present application was filed. They do not in any way affect the contents of the present application, but serve to prove that Product R and the "conventional Reticulose" are indeed two distinct products.

A patentee is free to be his or her own lexicographer. "When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning..." See MPEP 2173.05(a). It is up to applicant, not anyone else, to state what Product R is. Thus, the term "Product R" relates to only one product, that is, the product specifically defined in the present application at page 10, Method I. It is a clear and definite term.

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It should be noted that the "conventional Reticulose" has never been referred as "Product R". The term "Product R" was first used only by applicant in the present patent application and applicant's other patents or patent applications. In each such case, the term "Product R" was specifically defined by its manufacturing process in the application was filed, as the composition of Product R is extremely complex and had not been fully investigated. Applicant respectfully submits that such practice, i.e. defining a product by its manufacturing process is permissible by the PTO rules. *See* MPEP 608.01(v). While the Examiner has acknowledged that the process that defines Product R is different from the process for making Kochel's product but assumes that these two different processes would produce the same product. However, there is not a shred of evidence supporting such assumption. Indeed, all the existing information lead a conclusion contrary to the Examiner's assumption.

The present invention is directed to a novel method of treating an auto immune disease with Product R defined by a specific process. As a basic principle of the patent law, a method claim for treating one disease with one product is not anticipated by a teaching of a method for treating the same disease with a different product, absent any teaching or suggestion in the prior art. Whether Product R is same as or different from the "conventional Reticulose" or whether it contains Kochel's low molecular weight components is utterly irrelevant to the present invention because Kochel never teaches how to administer the "conventional Reticulose" nor his lower molecular weight components together with the high molecular weight components to treat auto immune diseases. Even assuming applicant's product is the "conventional Reticulose", a new use of the "conventional Reticulose" would not be anticipated by the same use of Kochel's lower molecular weight components because there is no teaching nor suggestion in the Kochel's patent that the "conventional Reticulose" has the same properties as its lower molecular weight components. The fact that the "conventional Reticulose" contains the Kochel's lower MW components does not by itself make the "conventional Reticulose" same as the lower MW

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components. In fact, Kochel makes it clear that only the lower molecular weight components, not the high molecular weight components nor the "conventional Reticulose", may be useful for treating auto immune diseases, as he states that "the active components of the conventional composition may be *segregated according to molecular weight and the different resulting groups of components may be selectively used* to treat different viruses and auto immune disease accordingly." Spec. col. 3 ll. 7-11.

While the "conventional Reticulose" includes Kochel's product because Kochel's product is derived from, therefore a part of the "conventional Reticulose", that is not the case of Product R. In the present application, Product R materially differs from the "conventional Reticulose". There is no basis to conclude that the use of Kochel's lower MW components anticipates the use of Product R.

There is another reason that the Kochel's patent cannot be an anticipatory prior art to the present invention. As a matter of law, a nonenabling reference does not anticipate. *United States v. Adams*, 383 U.S. 39, 50, 148 USPQ 479. Kochel's patent will not enable a person of ordinary skill in the art to treat auto immune disease using the lower molecular weight portion of the "conventional Reticulose" because there is not a single word in the patent that tells a person of ordinary skill in the art how to use such material other than an ambivalent suggestion that it *may be* used to treat auto immune disease. It is even a far more stretch to conclude that Kochel teaches how to use Product R, a product that is different from the "conventional Reticulose" and does not contain the Kochel's lower MW components, to treat auto immune disease.

Further more, it is not clear what exactly Kochel teaches. Kochel stated in the specification, col. 3, ll 1-7, that:

> "Further, although the lower weight active components (MW <8-15 kDa) of the composition are not effective s antiviral agents, they are effective in treating auto immune diseases such as *non-Hodgkins Lymphoma, Adult Onset Leukemia, AIDS, Lupus, Scleroderma, Epstein Barr virus, Cytomegalovirus, Chronic Fatigue Syndrome, Candidiasis, Rheumatoid and Osteo Arthritis*, etc.

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> Thus, the active components of the conventional composition may be segregated according to molecular weight and the different resulting groups of components may be selectively used to treat different viruses and auto immune diseases accordingly."

In the above paragraph, Kochel listed a number of auto immune diseases subject to the treatment. But known to a person of ordinary skill in the art, most of diseases on this list, such as *non-Hodgkins Lymphoma, Adult Onset Leukemia, AIDS, Scleroderma, Epstein Barr virus, Cytomegalovirus, Chronic Fatigue Syndrome, Candidiasis, and Osteo Arthritis*, are not auto immune disease at all. In fact, *non-Hodgkins Lymphoma, AIDS, Scleroderma, Epstein Barr virus, Cytomegalovirus, Chronic Fatigue Syndrome,* and *Candidiasis* are viral diseases. Does Kochel knows what he is talking about?

In that paragraph, Kochel first indicates that the lower MW components of the "conventional Reticulose" are not effective as antiviral agents, but effective in treating auto immune diseases. Then he names a number of diseases, most of them are viral diseases, as auto immune diseases to be treated. At most, the teaching in the Kochel patent is contradictory and incomprehensible. No person of ordinary skill in the art, following Kochel's teaching, would be able to practice this "invention", if it is considered an invention at all.

For the above reasons, applicant respectfully submits that the present invention is not anticipated, nor rendered obvious, by Kochel (U.S. pat. No. 5,849,196) and the rejection under 35 U.S.C 102(e) over Kochel should be withdrawn.

Rejection under 35 U.S.C. 112, second paragraph

The Examiner maintains the rejection under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particular point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner believes that the phrase "effective symptom ameliorating amount" and the term "Product R" are unclear.

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Applicant respectfully submits that the phrase "effective symptom ameliorating amount" must be read in conjunction with the following phrase "in a range from about 2.5 microliters to about 40 microliters per kilogram of body weight per day". Thus, the scope of the amount of Product R to be administered is clear. Alternatively, applicant will delete such phrase if the Examiner believes that the removal of this phrase will make the claim more clear and definite.

While applicant describes two methods of making Product R, for the purpose of the present invention, the term "Product R" is now defined by Method I on page 10 of the present application.

The Examiner further argues that there is "no standard levels of activity are set forth for the Product R preparations, nor does the specification indicate how activities of Product R are to be determined." It is unclear to applicant what the Examiner believes is missing here. Again, the present invention is directed to a method of treating auto immune disease, not Product R. As long as the present application provides sufficient information to enable a person of ordinary skill in the art to practice the present invention, it meets the requirements of 35 U.S.C. 112. In the instant case, preparation of Product R is described in great detail on page 10; method for treating rheumatoid arthritis by administering Product R is described from pages 12 to 2; and efficacy and testing results of Product R in treating rheumatoid arthritis are presented in Table 1 on page 19 and Figs. 1A, 1B, 1C, and 2-5. Applicant believes that these information are sufficient to enable a person of ordinary skill in the art to make and use the present invention. By requiring more, the Examiner appears to impose on applicant a more stringent standard that is not mandated by law nor by the rules of the Office.

It is also respectfully submit that the amount of Product R to be administered to a patient is described by either microliters/Kg/day (e.g. 2.5 microliters per kilogram of body weight per day) or milliliters/patients (e.g. 1 milliliter per patient). Assuming a person weights about 70

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kilogram, then 2.5/Kg/day equals to about 0.175 milliliters per such person, which is about 1/5 of 1 milliliter per patient. Thus, the claimed range is not unduly wide.

Accordingly, it is respectfully submits that the above two terms in question are now clear and definite and the rejection under 35 U.S.C. 112, second paragraph, should be withdrawn.

Any additional fees or charges required at this time in connection with the application may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,

COHEN, PONTANI, LIEBERMAN & PAVANE

By _____

Yunling Ren
Reg. No. 47,019
551 Fifth Avenue, Suite 1210
New York, N.Y. 10176
(212) 687-2770

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AMENDMENTS TO THE CLAIMS AND SPECIFICATION SHOWING CHANGES

Amend claim 1 as follows:

1. A method of ameliorating a symptom of rheumatoid arthritis in a patient suffering from rheumatoid arthritis, comprising parenterally administering to said patient an effective symptom ameliorating amount of Product R in a range from about 2.5 [microliter] microliters to about 40 microliters per kilogram of body weight per day in a pharmaceutically acceptable formulation.

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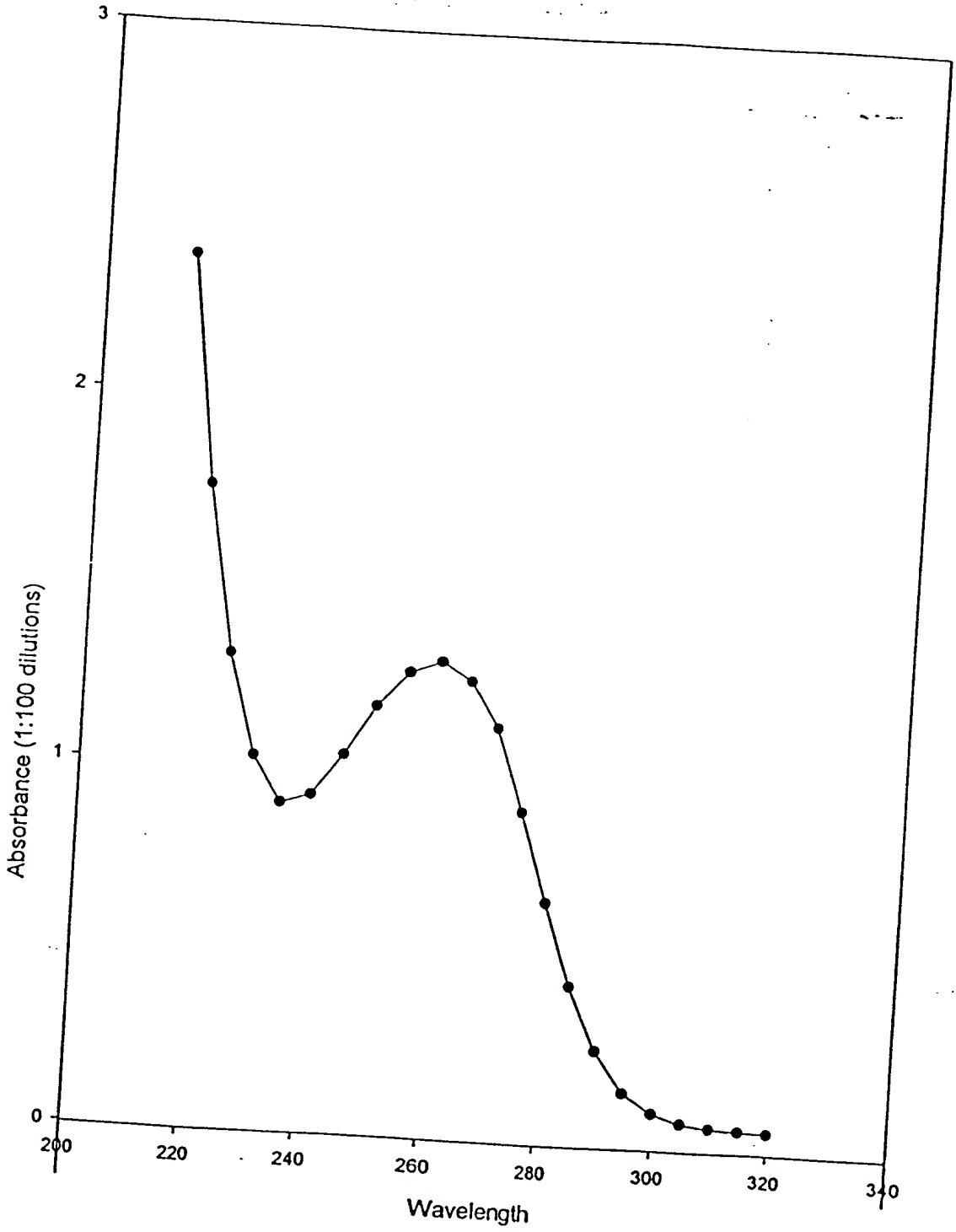
Figure 1

ULTRAVIOLET SPECTRUM OF Product R



The spectrum was obtained on a 1:100 dilution of Product R In distilled water and was recorded on a Shimadzu Model UV-1201 UV-VIS Spectrophotometer. The spectrum was recorded between 220-320 nm and shows an absorption maximum at 260 nm with a trough at 235 nm.

$A_{260/280} = 1.998$; $A_{260/230} = 1.359$

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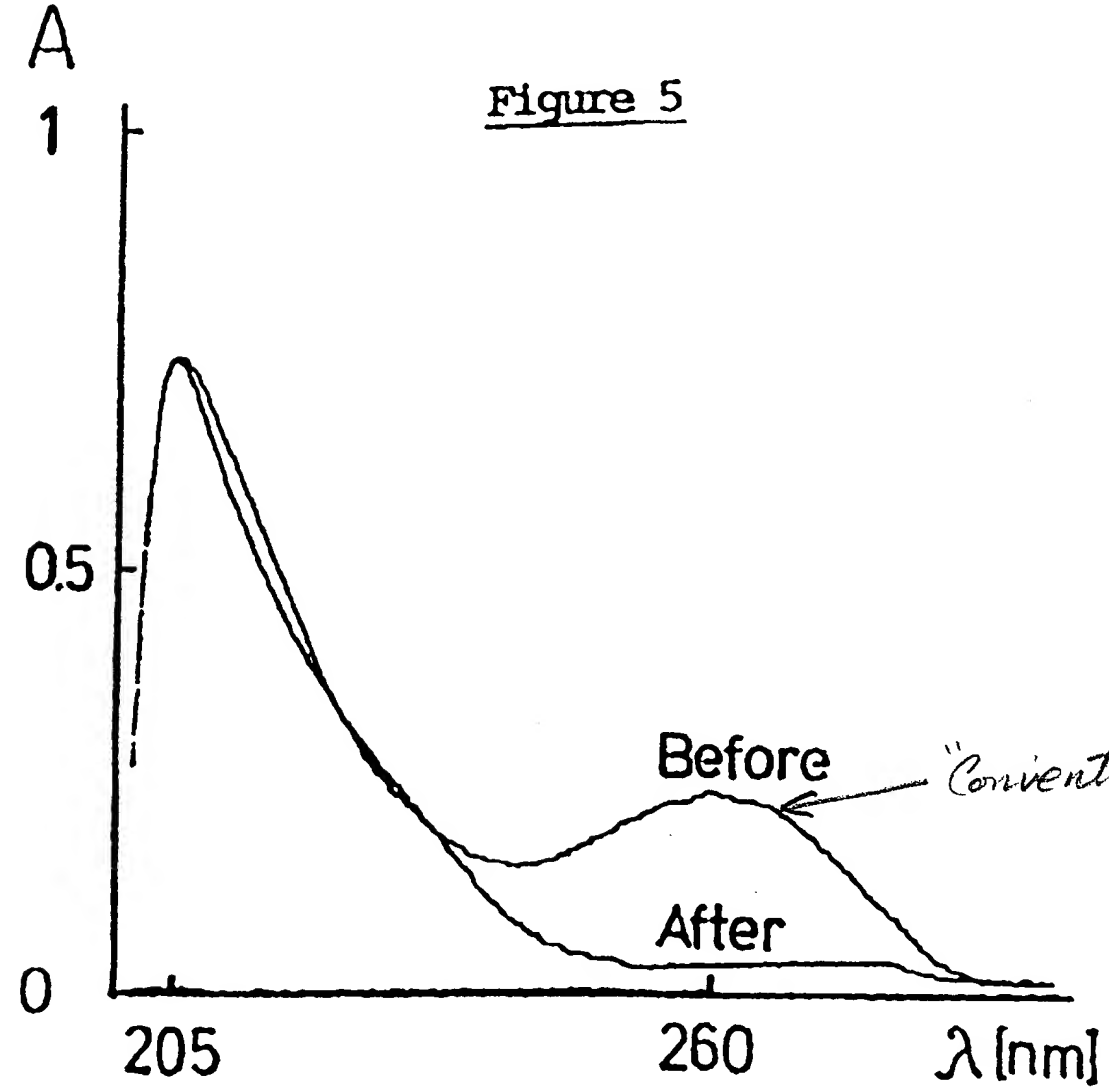
Figure 5



CPC [%]
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